REMARKS

Applicants have reviewed the application file and thank the Examiner for allowing time for further examination. Applicants respectfully request once more that the official records be corrected to reflect the correct filing date of December 4, 2001, of this divisional application, as requested on March 22, 2002, which does not appear on the recent Office communication.

1. Rejection of claims 1-3 and 5-7 on obviousness-type double patenting grounds

The Office Action asserts a rejection of claims 1-3 and 5-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,541,603. Applicants elect to postpone addressing this ground of rejection, by filing a Terminal Disclaimer pursuant to the provisions of 37 C.F.R. §1.321(c), once all other issues relating to patentability have been resolved.

3. Rejections of claims 1-3, and 5-7 under 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 1-3, and 5-7 under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement, as interpreted under the U.S. Patent and Trademark Office examination Guidelines and under the rubrics of *Reagents of the University of California v. Eli Lilly*, *Fiers v. Revel*, and *Amgen v. Chugai*. Applicants respectfully traverse these grounds of rejection as follows.

Applicants refer to the following quotation from the Written Description Guidelines published in the Federal Register on January 6, 2001:

> In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim ***other than*** *a product-by-process claim.* n52 *(emphasis added)*
>
> n52 *See, e.g., Fiers v. Revel, 984 F.2d at 1169, 25 USPQ2d at 1605; Amgen., 927 F.2d at 1206, 18 USPQ2d at1021.* Where the process has *actually been used to produce the product*, the written description requirement for a product-by-process claim is *clearly satisfied*; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process. *(Emphasis added)*

Applicants respectfully contend that the meaning of the Guidelines is clear: the issue in a product-by-process claim is whether there is an adequate written description of the *process*, and sufficient

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evidence that the process produces the product. According to the Guidelines, it is impermissible for the Office to require that Applicants describe anything more than this to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

Applicants respectfully contend that pending independent claims 1-3 and 8 disclose synthetic peptides having an amino acid sequence encoded by sense-oriented genetic suppressor elements produced by a method for preparing such elements, the strength of which method is that *absolutely nothing* need be known about the chemical or genetic structure of the genes and proteins responsible for the transformed phenotype in order to obtain said elements. Unlike the prior art, which *required* the isolation of a functional gene in order to develop what were termed "dominant negative mutants," the present invention provides an efficient method for producing specific, functional genetic suppressor elements from genes responsible for the transformed phenotype in mammalian cells. This is accomplished in the complete absence of *a priori* knowledge of the chemical or genetic structure of such genes. Applicants respectfully contend that these claims are in the nature of "product-by-process" claims that are recognized under the patent law to be an acceptable method of claiming chemicals *for which the structure is unknown.*[1]

Applicants respectfully contend the Office has failed to set forth any evidence that would call into question whether the acts set forth in the specification can be performed, or any evidence that he product is produced by that process. There being no other basis in the explicit language and directive of the Guidelines providing any support for rejection of product-by-process claims for any other reason, the Office has not overcome the presumption that the claims as filed fulfill the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants further respectfully contend that they have complied with both the Guidelines and the law, and that their claims are in condition for allowance. Applicants also request that any further communication forthcoming from the Office, other than a Notice of Allowance, set forth the grounds under which the clear import and meaning of the Guidelines are not to be followed in this case, to better

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[1] While fully aware that each application and the claims therein are examined independently, Applicants note for the record that product-by-process claims of similar scope have been granted in related applications. *See, for example*, U.S. Patent Nos. 6,541,603, issued April 1, 2003; 6,376,24, issued April 23, 2002; 6,326,488, issued December 4, 2001; 6,281,011, issued August 28, 2001; 6,083,746, issued July 4, 2000; 6,083,745, issued July 4, 2000; 6,060,244, issued May 9, 2000; and 6,043, 340, issued March 28, 2000.

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clarify the issues for appeal.

CONCLUSIONS

Applicant believes that all requirements of patentability have been fully met, and allowance of the claims is respectfully solicited.

If the Examiner in charge of this application believes it to be helpful, he is invited to contact the undersigned attorney by telephone at (312) 913-0001.

Respectfully submitted,
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